DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Philips Medical Systems Nederland B.V.
Susan Quick
Regulatory Affairs Specialist
595 Miner Rd
CLEVELAND OH 44094

March 20, 2015

Re: K143128
Trade/Device Name: mDIXON XD
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: February 06, 2015
Received: February 20, 2015

Dear Ms. Quick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143128

Device Name
mDIXON XD

Indications for Use *(Describe)*

mDIXON XD is a software option intended for use on Achieva, Ingenia 1.5T & 3T MR Systems. It is indicated for use in Magnetic Resonance Imaging of the human body. mDIXON XD is an enhanced 2-point fat-free mDIXON technology, available for gradient echo and spin echo acquisitions. mDIXON XD enables the combination of a fat-free technology with the MultiVane XD motion-free technique for anatomies such as head. mDIXON XD also enables subtractionless MR Angiography in areas of the body where exogenous contrast media has been approved for MR imaging.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Philips Medical Systems Nederland B.V.

510(k) Summary

mDIXON XD

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. General Information
21 CFR 807.92 (a)(1), (2)

Company Name:	Philips Medical Systems Nederland B.V.
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Registration No.:	3003768277
Contact Person:	Susan Quick 595 Miner Rd Cleveland, Oh 44143 Tel: (440)-483-2291 Fax: (440)-483-4799 E-mail: susan.quick@philips.com
Prepared (date):	2014 October 29
Trade Name of Device:	mDIXON XD
Classification:	Class II
Regulatory Section:	Magnetic Resonance Diagnostic Device. 892.1000
Product Code:	90LNH

21 CFR 807.92(a)(3):Legally marketed predicate device to which substantial equivalence is claimed:

1. Primary Predicate Device: mDIXON
   Manufacturer: Philips Healthcare
   Predicate Device k#: K102344

2. Reference Devices: MultiVane and e-THRIVE (Ingenia MR System)
   Manufacturer: Philips Healthcare
   Predicate Device k#: K110151

21 CFR 807.92(a)(4): Description of the device that is the subject of this premarket notification:

Summary of functions of the device and its major components

mDIXON XD provides an improved water/fat reconstruction algorithm (7-peak fat modeling, B0-correction and fat-shift correction). mDIXON XD relies on the 2-point mDIXON fat-free technology making use of unrestricted echo times and is capable of generating four image contrasts (Water, Fat, In-Phase, Out-Phase) in one scan. mDIXON XD can be used with the following:

- Multivane XD (motion correction) for the head
- MR Angiography (subtractionless MRA), removes the need for the subtraction of the pre- and post-contrast enhanced images.
- Gradient echo (FFE – Fast Field Echo) and turbo spin echo (TSE) sequences to achieve efficient fat-free scanning compatibility, even at large FOV or sub-millimetric resolutions

mDIXON XD is supported on the following systems:

- 3.0T Ingenia
- 3.0T Achieva
- 1.5T Ingenia
- 1.5T Achieva

The functionality is supported on all available gradient performance levels. Optimized protocols will be provided for the different performance points. mDIXON XD is supported on the centralized data acquisition systems of the Achieva systems as well as the digitally networked data acquisition system of the Ingenia systems. The data acquisition system is fully transparent to the pulse sequences and mDIXON XD reconstructions.

21 CFR 807.92(a)(5): Intended Use

mDIXON XD is a software option intended for use on Achieva, Ingenia I .5T & 3T MR Systems. It is indicated for use in Magnetic Resonance Imaging of the human body. mDIXON XD is an enhanced 2-point fat-free mDIXON technology, available for gradient echo and spin echo acquisitions. mDIXON XD enables the combination of a fat-free technology with the MultiVane XD motion-free technique for anatomies such as head. mDIXON XD also enables subtractionless MR Angiography in areas of the body where exogenous contrast media has been approved for MR imaging.

21 CFR 807.92(a)(6): Technological Characteristics:

The main functional units in the software are:

- MRChains (software for controlling and diagnosing the hardware)
- Methods (acquisition of MR signals by means of MR pulse sequences)
- Reconstruction (transforming the MR signals to images)
- Patient Administration (storing of the images in the database and providing access)
- Viewing (display of images)

The impact of mDIXON XD on these functional units are:

- MRChains: Provide static B0-field information, as measured at system installation time.
- Methods: Use an existing multi-echo (usually 2 echoes) FFE, TFE or multi-acquisition TSE for mDIXON XD, within the cleared limits provided by the basic MR system. The requested output image types can be specified by the user in the scan protocol.
- Reconstruction: Add a new calculation function that calculates water, fat, IP and OP images. Apply a fat-peak-model and B0-field information to separate water from fat. Make use of water-fat shift correction and geometry correction.
- Patient Administration and Viewing: enable storage and display of the output images with appropriate labels (water, fat, IP, OP)

No off-the-shelf software is used for mDIXON XD. The off-the-shelf software used in the basic MR system is cleared. mDIXON XD is not designed to be connected to an external network. mDIXON XD does not require any change of the hardware platform. The major extensions introduced by mDIXON XD are in methods pulse sequence code, and in reconstruction for the enhanced calculation. Those run on the host computer:

Computer characteristics:

- Manufacturer: HP; Model: Z420; Processor clock: 3.5 GHz; RAM: 64 GB RAM; Processors: six core with hyper threading
- Operating system: Windows 7, 64 bits

Changes to operator workflow for mDIXON XD are:

- Protocol selection: The operator selects an ExamCard with mDIXON XD protocols
- Planscan phase: Optionally the operator may want to change the predefined selection of output image-types.
- For mDIXON XD MRA: During scanning no pre-contrast baseline has to be scanned, saving one multi-station table-stroke, compared to conventional MRA.

All other steps are not changed. The generated image types can be viewed, post-processed, printed

and archived as any other image type.

21 CFR 807.92(b)(1): Brief discussion of nonclinical tests submitted, referenced or relied on in this premarket notification:

mDIXON XD has been verified to function with the Achieva and Ingenia 1.5T and 3.0T MR systems.

The verification testing showed the examcards could be loaded, the correct parameters were listed for each scan, there were no issues when turning on SENSE, the four image types could be selected, all scans ran properly and images were provided.

The conclusion from this report is:

All the tests performed for mDIXON XD were successful. Workflow was smooth and no problems occurred.

All defects have been corrected.

21 CFR 807.92(b)(2): Brief discussion of clinical tests submitted, referenced or relied on in this premarket notification:

Clinical user needs are tested as part of validation. The validation testing showed that for total body and head/neck examinations, the Image Quality, fat suppression and fat suppression over large FOV was similar or better with mDIXON XD compared to e-Thrive. For cardiac examinations the image quality and fat suppression were better with mDIXON XD. For MultiVane XD in combination with mDIXON TSE, the motion related artifacts were reduced compared to mDIXON TSE alone and the MultiVane XD with mDIXON XD can be used with T2 in head imaging.

The conclusion from testing the device is:

The clinical validation of mDIXON XD has completed successfully. All clinical user needs have passed for mDIXON XD on the Achieva and Ingenia 1.5T and 3T systems.
All defects have been analyzed and are verified to be solved and will be closed, no new hazards were identified.

21 CFR 807.92(b)(3): The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section:

The nonclinical and clinical tests have demonstrated that the device is safe and works according to its intended use**.**

mDIXON XD software does not introduce new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers mDIXON XD Software to be substantially equivalent to the above mentioned predicate device.